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PTO/SB/21 (09-04)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Total Number of Pages in This Submission	

Application Number	09/863,316-Conf. #1362
Filing Date	May 24, 2001
First Named Inventor	Jin Zongxuan
Art Unit	1614
Examiner Name	D. A. Jagoe
Attorney Docket Number	GOT-0011

ENCLOSURES (*Check all that apply*)

- [ ] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
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  - [ ] Affidavits/declaration(s)
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- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to TC **(Reply Brief)**
- [ ] Proprietary Information
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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	RADER, FISHMAN & GRAUER PLLC		
Signature			
Printed name	David T. Nikaido/Lee Cheng		
Date	May 6, 2005	Reg. No.	22,663/40,949

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Jin Zongxuan

Application No.: 09/863,316 Confirmation No.: 1362

Filed: May 24, 2001 Art Unit: 1614

For: SKIN CANCER PREVENTIVE AGENT Examiner: D. A. Jagoe

REPLY BRIEF

MS Appeals-Patent
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a Reply Brief under 37 C.F.R. §41.41 in response to the Examiner's Answer mailed on March 9, 2005.

All arguments presented within the Appeal Brief of October 21, 2003 are incorporated herein by reference. Additional arguments are provided herein below.

In the Examiner's Answer, the Examiner has maintained the rejection of claims 5-12 under 35 U.S.C. §112, first paragraph, since the experimental results in the specification is "*insufficient to establish the generic concept*" of the present invention (i.e. *method of inhibiting skin cancer*). The Examiner also argues that the claims are not limited to the "*specific action caused by a specific cancer promoters, DMBA and TPA,*" and that the data is "*not statistically significant to scientifically show that the results obtained accrues from the method used*". However, Applicant strongly disagrees with the Examiner in this regard.

The experimental results are sufficient to establish the generic concept of the present invention since the experimental data clearly shows that administration of the claimed composition (*comprised of sericin*) inhibits skin cancer when skin is exposed to cancer promoters. The Examiner has argued that skin cancer have potentially many different causes such as heredity and environment, which has not been address by the teachings in the

specification. However, the Examiner fails to consider that the formation of all skin cancer cells is the result of damages to cells (genomic damage) which cause the cells to grow uncontrollably. Such damages can be caused by a variety of factors such as heredity and environment. However, if a compound or composition can protect the cells from damage by preventing, for example, mutations in DNA replication, such compound or composition will be effective in inhibiting skin cancer regardless of cause since the action of the compound or composition is on the cell itself. Applicant believes that the experiment results in the specification demonstrate that administration of the claimed composition (*comprised of sericin*) inhibits skin cancer by protecting the skin cells from genomic damage.

Such a showing of efficacy by the experimental data precludes the need to limit the claims to the "*specific action caused by specific cancer promoters, DMBA and TPA*" since the administration of the claimed composition enables the inhibition on skin cancer under multiple factors.

Applicant also believes that the experimental data in the specification is "*statistically significant to scientifically show that the results obtained accrue from the method used*". As is clear from the results show in FIG. 1 of the drawings, although initial papilloma occurred in week 8 in the control group to which only acetone solutions of DMBA and TPA were applied, in test group A to which the claimed composition (comprised of sericin) was applied, initial papilloma did not occur until week 14. In addition, as a result of comparing the number of papilloma in week 20, the occurrence of papilloma was found to be inhibited by 80% in test group A as compared with the control group. Thus, the experimental results clearly show that the claimed composition exhibit preventive effects on the occurrence of papilloma on mice skin.

Further, when the numbers of papilloma were determined in the test groups in week 20 in order to investigate the concentration-dependent inhibitory action of sericin on the number of papilloma on mice skin, the number of papilloma was lower in test group B, in which the total amount applied was 5 mg, than in test group A, in which the total amount applied was 2.5 mg. In addition, when test group B was compared with the control group in week 20, an inhibition rate of 100% was demonstrated in test group B. On the basis of these findings, it is clear that the larger the sericin concentration (applied amount), the greater the preventive effect of the claimed composition on the occurrence of mouse skin papilloma.

Applicant wishes to emphasize that under U.S. practice, only a reasonable correlation between the evidence of pharmacological or other biological activity of a compound and the

asserted therapeutic utility is required. Applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does Applicant have to provide actual evidence of success in treating humans where such a utility is asserted. Instead, as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. *Nelson v. Bowler*, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980).

In addition, data generated using *in vitro* assays, or from testing in an animal model or a combination thereof (if reasonably correlated to the particular therapeutic or pharmacological utility) is sufficient to establish therapeutic or pharmacological utility for a compound, composition or process. The evidence does not have to be in the form of data from an art-recognized animal model for the particular disease or disease condition to which the asserted utility relates. Data from any test that Applicant reasonably correlates to the asserted utility should be evaluated substantively and accepted.

Thus, in view of U.S. case law, the experimental data in the specification is "*statistically significant to scientifically show that the results obtained accrue from the method used*".

With regard to the rejection of claims 5-12 under 35 U.S.C. §103(a), Applicant believes that there exist an inherent contradiction between the Examiner's arguments in this §103 rejection and the rejection under 35 U.S.C. §112, first paragraph.

To establish a *prima facie* case of obviousness, the following three criteria must be satisfied. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Finally, there must be a reasonable expectation of success. Based on the Examiner's arguments in the rejection under 35 U.S.C. §112, first paragraph, Applicant cannot reason how the Examiner can argue that there is a reasonable expectation of success to modify the teachings of Yamada et al. to arrive at a method of inhibiting skin cancer by administering a composition comprised of seracin.

As the Examiner notes on pages 5 and 6 of the Examiner's Answer, in order to enable a method of inhibiting skin cancer, one skilled in the art would have to first envisioned a cause of the skin cancer, then a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, and appropriate animal model system and test the

combination of the model system to determine whether or not the combination is effective for inhibition of skin cancer. If unsuccessful, one skilled the art would then have to modify the process above or envision an entirely new process.

Yamada et al. discloses the use of sericin as antioxidants and tyrosinase inhibitors. Antioxidants and tyrosinase inhibitors are used to prevent discoloration in foods and to prevent blotching of skin color caused my melanin formation. Yamada et al. does not specifically teach the use of sericin to inhibit skin cancer. In addition, Yamada et al. do not teach any of the above elements (i.e. *appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, appropriate animal model system, etc.*) which would demonstrate to one skilled in the art that there is a reasonable expectation of success to modify the teachings of Yamada et al. to arrive at the method of the present invention.

Thus, even though Applicant does not agree with the Examiner's arguments in this regard, Applicant respectfully request the Board to reconcile this apparent contradiction in the rejections under 35 U.S.C. §112, first paragraph, and §103(a).

CONCLUSION

For at least the reasons set forth hereinabove, the rejection(s) of the claimed invention should not be sustained.

Therefore, a reversal of the Final Rejection of May 21, 2003 is respectfully requested.

If any fee is required or any overpayment made, the Commissioner is hereby authorized to charge the fee or credit the overpayment to Deposit Account # 18-0013.

Dated: May 6, 2005

Respectfully submitted,

By_____
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